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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,773	05/13/2005	John Forsyth Russell Robertson	02332-0050 (315804)	1789

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,773	ROBERTSON ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *9,10,15,16 and 19-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-38 are all the pending claims for this application.

2. Applicant's amendment of Claims 3-9, 12, 14, 15 and 18 from reciting a "use" to "a method" is acknowledged and entered.

3. Applicant's amendment of Claims 12 and 14-18 to bring the claims into proper dependency is acknowledged and entered.

4. Applicant's amendment of Claim 1-18 to correct informalities, spelling and for clarity is acknowledged and entered.

Election/Restrictions

5. Applicant's election with traverse of Group I (Claims 1-8 and 11-18) in the reply filed on 1/29/07 is acknowledged. The traversal is on the ground(s) that "the IPER for the international application, completed on 11/1/05, does not indicate a lack of unity under PCT Rule 13."

This is not found persuasive because 37 CFR 1.499 (MPEP 1893.03(d)) provides that an examiner may require the restriction of claims for a national stage application that lacks unity of invention under §1.1475. Additionally, Applicant has not provided any technical arguments why the lack of unity restriction is improper or why the inventive groups are not coextensive for searching purposes.

Further Applicant's argument for rejoinder of Groups I and II because Claims 9 and 10 of Group II are dependent from Claim 1 of Group I, has been considered but is not found persuasive. Each of Claims 9 and 10 are drawn to patentably distinct methods

as discussed under section 7 of the Office Action of 9/27/06. Claim 9 requires the additional step of determining the robustness or strength of a patient's overall immune response, and Claim 10 is drawn to administering a protein or nucleic acid vaccine and measuring any cancer-associated antibody.

The requirement is still deemed proper and is therefore made FINAL.

6. Applicant's election of species for ras as the tumor marker protein is acknowledged. It is noted that the elected species does not read on elected Claims 15 and 16 of Group I.

7. Claims 9, 10, 15, 16 and 19-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions (Claims 9, 10 and 19-38) and non-elected species (Claims 15 and 16), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/29/07. Further the non-elected species for tumor marker protein of Claims 17 and 18 are withdrawn.

8. Claims 1-8 and 11-14, 17 and 18 are all the pending claims under examination.

Information Disclosure Statement

9. The U.S., international and foreign patent references and non-patent literature references cited in the IDS of 12/14/06 have been considered and entered with the exception of ref. #10 (JP 09 189702). The IDS fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; a copy of reference #10 was not enclosed. Reference #10 has been stricken from the IDS. Should

Applicant's wish to have the reference considered, they are invited to furnish a copy with the Response to this Action.

Oath/Declaration

10. The oath or declaration is defective. A new oath or declaration or copies of the original executed oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants are invited to verify the non-initialed alterations on pp. 3 and 4 of the file copy by accessing the document through the PAIR system.

Specification

11. The specification is objected to for the following reasons:

a) The specification is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). Applicants are invited to verify the non-initialed alterations on p. 1 of the file copy by accessing the document through the PAIR system.

b) The specification does not cross-reference related applications.

c) The use of the trademark PinPoint ™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicants are advised to carefully check the specification for any other trademarks that may not be properly identified.

Claim Objections

12. Claims 2, 11 and 13 are objected to for the following reasons:

a) Claim 2 (2nd "wherein" clause) is objected to for reciting duplicate claim language- "of".

b) Claims 11, 13 and 17 are objected to as depending from non-elected claim 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-8, 11-14, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1-8, 11-14, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the relationship between the sample on which the method steps are being performed and the tumor marker proteins prepared from bodily fluids or excretions from one or more cancer patients. Is there a relationship between the kind or type of cancer that the autoantibodies are directed against and the cancer patients from which the immunoassay reagents are obtained? The claims do not describe whether the same cancer or similar cancers (e.g., stage) are considered in performing the method.

b) Claims 1-8, 11-14, 17 and 18 are indefinite for the recitation "one or more tumor marker protein prepared from a bodily fluid, derived from a body cavity or space" because in Claims 1 (1st "wherein" clause), 2 (2nd "wherein" clause), 11 and 12, the meaning of the term "derived" is not clear. The term "derived" is not one which has a universally accepted meaning in the art nor is it one which has been adequately defined in the specification. The primary deficiency in the use of this term is the absence of an

ascertainable meaning. Since it is unclear how the bodily fluids are to be derived from a body cavity or space, the term can encompass body fluids that are pre-filtered or pre-adsorbed or which have undergone any number of different steps after being removed from the body cavity or space prior to the protein being prepared from the fluid sample. Would the "prepared" tumor protein be any different than the protein found in the fluid of a body cavity or space?

c) Claims 1-8, 11-14, 17 and 18 are indefinite for the recitation "with which is or was associated" because in Claim 1 it is not clear whether the bodily fluid or the tumor is being referred to in the claim.

d) Claims 2-8 and 11-14, 17 and 18 are indefinite for the recitation "one or more of detecting or quantitatively measuring a presence of two or more types of autoantibodies" because in Claim 2, it is not clear what other method steps constitute "more" than the "detecting" and "quantitatively measuring" steps. The method involves performing either one or both the steps.

e) Claims 2-8 and 11-14, 17 and 18 are indefinite for the recitation "or to of same tumor marker protein" because in Claim 2 (1st "wherein" clause) it is not clear what the intended immunological specificity is for the autoantibody.

f) Claims 17 and 18 recite improper Markush group language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-8, 11-14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06).

Claims 1-8, 11-14, 17 and 18 are drawn to an immunoassay method of detecting antitumor autoantibodies comprising contacting a sample being tested for an autoantibody with an immunoassay reagent and detecting the formation of a complex between the immunoassay reagent and the autoantibody, where the immunoassay reagent is one or more tumor marker proteins prepared from a bodily fluid derived from a body cavity or space where a tumor is or was present or associated and being from one or more cancer patients, or an excretion from one or more cancer patients, and where one or more tumor marker proteins are selectively reactive with the anti-tumor autoantibodies, and methods involving detecting and quantifying two or more autoantibodies that are reactive with two or more tumor marker proteins, and methods of detecting or diagnosing cancer, and methods of monitoring progress of cancer or

other neoplastic disease, or methods of detecting in an asymptomatic subject an early neoplastic or early carcinogenic change, and methods of screening asymptomatic subjects at risk of developing cancer, and methods of monitoring a response of a cancer patient to anti-cancer treatment, and methods of detecting a recurrent disease in a subject having undergone anti-cancer treatment, where the bodily fluid is a pleural effusion and the excretion is urine, and where the tumor marker protein is ras.

Robertson teaches that tumor marker proteins can elicit serum autoantibodies. Robertson teaches methods for detecting these autoantibodies (p. 3, lines 3-7; p. 5, lines 23-34) using a panel of isolated tumour marker antigens in an immunoassay format as immunoassay reagents (p. 6, line 14- p. 7, line 7), where the panel of tumor antigens may be tailored to detect a particular cancer, or a cancer at a particular stage of development, where the tumor antigens are isolated from samples of biological fluid from one or more normal or cancerous patients (p. 7, lines 10-20), and the assay comprises one or more of the tumor marker antigens for detecting and quantitating the presence of one or more autoantibodies by autoantibody/antigen complex (p. 6, lines 25-31; p. 10, line 28- p. 11, line 25). The isolated tumor marker proteins from bodily fluids of cancer patients that can be obtained from a cavity or space include pleural effusions (Figure 11), and those from an excretion of cancer patients include urine (Figure 2). Robertson teaches detecting autoantibodies against the ras tumor marker protein (p. 8, line 10). Robertson teaches the versatility of the assay for a variety of clinical applications including detection of primary or secondary in screening for early neoplastic or early carcinogenic change in asymptomatic patients or identification-of

individuals 'at risk' of developing cancer in a population or asymptomatic individuals, in the detection of recurrent disease in a patient previously diagnosed as carrying tumour cells who has undergone treatment to reduce the number of tumour cells or in predicting the response of an individual with cancer to a course of anti-cancer treatment (p. 9, lines 17-30).

The claims are anticipated by Robertson for the reasons set forth above.

16. Claims 1, 3, 4, 11 and 12 are rejected under 35 U.S.C. 102(b) as being by anticipated by Luo et al. (British J. Can. 87:393-343 (7/29/2002); cited in the PTO form-892 of 9/27/06).

The interpretation of Claims 1, 3, 4, 11 and 12 is discussed supra.

Luo teaches methods for detecting and quantifying autoantibodies in cancer patient samples. Luo teaches screening an ovarian cancer cDNA library with pooled ascites fluid from five different primary ovarian cancer patients to detect immunoreactive proteins. Table 1 lists the proteins identified as tumor antigens. Of those antigens, hsp90 was further studied, where the isolated hsp90 protein was reactive in immunoassays for detecting cancer patient autoantibodies in serum from stage III/IV and stage I/II ovarian cancer, breast cancer, colorectal cancer, and benign gynecological disease (Table 2). Luo postulates that mutations in the genes encoding these proteins results in autoimmune responses (p. 342, Col. 1, ¶1), and that the correlation of hsp90 autoantibodies and late stage ovarian cancer implies it may have utilities as a novel prognostic biomarker for ovarian cancer.

Because the phrase in Claim 1, "one or more tumor marker protein prepared from a bodily fluid derived from a body cavity or space", is indefinite as discussed supra, the screening of the ovarian cancer cDNA library with autoreactive antibodies from pooled ovarian cancer patient ascites, and the further characterization of the selected hsp90 protein, could be interpreted as reading on the phrase with respect to the aspect of preparing the tumor marker protein, and therefore the claims are anticipated by Luo.

17. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanash et al. (WO 00/26668; published 5/11/2000; cited in the IDS of 12/14/06).

The interpretation of Claims 1-7 is discussed supra.

Hanash teaches immunoassay methods for detecting autoantibodies in samples against cancer or tumor-derived family of S100 proteins where the S100 proteins are obtained from bodily fluids or a wide variety of protein mixtures containing S100 proteins (p. 6, line 3). Hanash discloses four S100 proteins, specifically, S 100-AG, S 100-A7, S 100-A8 and S100-A9, and using these isolated proteins in immunoassays for detection of autoantibodies. Hanash discloses that S100-A9 is found in colon and lung cancer patients and S100-A7 and S100-A8 proteins are found in breast cancer patients (p. 10, lines 10-15). Therefore to practice the method of Hanash requires obtaining bodily fluids from one or more cancer patients in order to prepare one or more S100 tumor marker proteins (i.e., S 100-AG, S 100-A7, S 100-A8 and S100-A9) as an immunoassay reagent. Hanash discloses using the methods for detection and quantitative measurement of S100 autoantibodies and in screening subjects for risk of cancer or

other proliferative diseases (p. 6, lines 9-12) or for the early diagnosis of diseases such as cancer or monitoring of autoantibody levels to prognostically to stage the progression of the disease (p. 11, lines 1-4) or monitoring the efficacy of various therapeutic treatments for cancer (p. 4, line I p. 5, line 1).

Because the generic claims are not drawn to any species of tumor marker protein, the methods using S100 proteins of Hanash read on and therefore anticipate the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-8, 11-14, 17 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4,

8 and 9 of copending Application No. 10/417,633 ("the '633" application; US 20030232399) in view of Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06).

The interpretation of Claims 1-8, 11-14, 17 and 18 is discussed supra.

The claimed methods were prima facie obvious at the time of the invention over Claims 1, 4, 8 and 9 of the '633 application in view of Robertson.

Claims 1, 4, 8 and 9 of the '633 application are drawn to a method of detecting the immune response to tumor marker proteins comprising contacting tumor marker antigens including ras with a sample and determining the presence of complexes formed between the tumor marker antigen and autoantbodies present in the sample, where the method can be used for detecting early neoplastic or early carcinogenic change in asymptomatic patients, in the detection of recurrent disease in a patient previously diagnosed as carrying tumour cells, which patient has undergone treatment to reduce the number, in the identification of those individuals which are at increased risk of developing cancer in a population of asymptomatic individuals, and predicting the response of an individual with cancer to an anti-cancer treatment. Claims 1, 4, 8 and 9 of the '633 application do not recite that the tumor marker protein should be prepared from bodily fluids or excretions derived from one or more cancer patients. Robertson rectifies this deficiency in it's disclosure.

The interpretation of Robertson is discussed supra.

It would have been prima facie obvious to have produced the method of detecting anti-tumor autoantibodies by immunoassay methods over Claims 1, 4, 8 and 9

of the '633 application in view of Robertson, because Robertson teaches the same methods, and isolating tumor marker proteins from pooled cancer patient bodily fluids or excretions such as plural effusions or urine from which the tumor markers are obtained in order to provide immunoassay reagents for detecting the autoantibodies in the samples being tested. Because both the claims and Robertson teach different tumor marker proteins of one or more or two or more, it is inherent to the assay system that two or more types of autoantibodies would bind to the respective tumor marker proteins.

For all of these reasons, the claimed invention was prima facie obvious at the time the invention was made over Claims 1, 4, 8 and 9 of the '633 application in view of Robertson.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-8 and 11-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8, 19, 20 and 24 of copending Application No. 09/881,339 ("the '339" application; US 20030138860) in view of Robertson et al. (WO 99/58978; published November 18, 1999; cited in the PTO form-892 of 9/27/06).

The interpretation of Claims 1-8 and 11-14, 17 and 18 is discussed supra.

The claimed methods were prima facie obvious at the time of the invention over Claims 1, 4, 8, 19, 20 and 24 of the '339 application in view of Robertson.

Claims 1, 4, 8, 19, 20 and 24 of the '339 application are drawn to a method of detecting the immune response to tumor marker proteins comprising contacting tumor marker antigens including ras with a sample and determining the presence of complexes formed between the tumor marker antigen and autoantbodies present in the sample, where the method can be used for detecting early neoplastic or early carcinogenic change in asymptomatic patients, in the detection of recurrent disease in a patient previously diagnosed as carrying tumour cells, which patient has undergone treatment to reduce the number of tumor cells, in the identification of those individuals which are at increased risk of developing cancer in a population of asymptomatic individuals, and predicting the response of an individual with cancer to an anti-cancer treatment. Claims 1, 4, 8, 19, 20 and 24 of the '339 application do not recite that the tumor marker protein should be prepared from bodily fluids or excretions derived from one or more cancer patients. Robertson rectifies this deficiency in it's disclosure.

The interpretation of Robertson is discussed supra.

It would have been prima facie obvious to have produced the method of detecting anti-tumor autoantibodies by immunoassay methods over Claims 1, 4, 8, 19, 20 and 24 of the '339 application in view of Robertson, because Robertson teaches the same methods, and isolating tumor marker proteins from pooled cancer patient bodily fluids or excretions such as plural effusions or urine from which the tumor markers are obtained in order to provide immunoassay reagents for detecting the autoantibodies in the samples being tested. Because both the claims and Robertson teach different tumor

marker proteins of one or more or two or more, it is inherent to the assay system that two or more types of autoantibodies would bind to the respective tumor marker proteins.

For all of these reasons, the claimed invention was prima facie obvious at the time the invention was made over Claims 1, 4, 8, 19, 20 and 24 of the '339 application in view of Robertson.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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